DuPont Nonwovens

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Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1006 (HFA-305)
Rockville, MD 20852

DuPont appreciates the opportunity to comment on the **"Premarket Notification 510(k) Submissions for Medical Sterilization Packaging Systems in Health Care Facilities: Draft Guidance for Industry and FDA".**

For ease of reference the section of the draft is annotated and the comment is included under the *Comment* heading.

1. Section I, Para A. (page 2) – The introductory paragraph states that " This guidance also covers reusable cassettes and trays provided by instrument manufacturers that are intended to be reused by the health care facility."

   Comment: Does the agency intend to cover those reusable cassettes and trays provided by other than **instrument** manufacturers?

2. Section I, Para B. Sub 1. (page 3) – The draft states that " Trays and cassettes intended to be used only for storage or transportation, and not for sterilization" are excluded.

   Comment: Does the agency intend to require labeling of trays and cassettes to enable the user and provider to differentiate those that are intended for sterilization and are covered by the guidance from those that are excluded? If so, that requirement needs to be added.

3. Section I, Para B. Sub 3. (page 3) – The draft states that " Cassettes or trays used for the packaging of single use devices that are intended to be reused" are excluded.

   Comment: The reference is not clear as to which item is not intended to be reused, the device or the packaging. In either case, if the hospital will use the cassettes or trays for sterilization, why should it not be covered by this guidance?

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4. Section I, Para C. (page 3). The draft states that there is "No consensus definition available" for Cassettes, Sterilization.

   Comment: The reason for the lack of consensus is that these cassettes do not provide a sterile barrier. The agency should consider including this key component in the definition.

   The draft states that "To maintain sterility, they are enclosed in a sterilization wrap."

   Comment: In addition to a sterilization wrap, they may be placed in a rigid container, pouch or reel good. The agency should expand the definition to include the alternatives.

5. Section I, Para C. (page 4)
   Comment: Polymeric materials are included in the draft document and should be defined in the definitions section.

6. Section I, Para C. (page 5) - The definition of Sterilization Medical Packaging Systems states that "They are intended to allow sterilization of the enclosed device"

   Comment: In addition to the definition provided by the agency, a key feature of medical packaging systems is to "maintain the sterility of the enclosed device until the point of use". The definition should be expanded to include this vital performance feature.

7. Section I, Para F. Sub 5. (page 7) – The draft states that "extension of shelf life based on FDA accepted protocols in the original 501K".

   Comment: It is unclear if the agency is referencing the shelf life of the container itself or the shelf life of the sterilized device after sterilization. If the reference is the device, the shelf life is event and device related and hence should not be included. If the shelf life reference is to the container, this may be dependent on cycle exposure as well as frequency of use and those parameters should either be included or be removed.

8. Section II, Para. C (page 8) – The draft states that the 510(k) cover letter and introductory information include an "Indication for Use Statement" that includes the cycle parameters for which the packaging systems are intended to be used.

   Comment: It is not possible for the packaging system manufacturer to know this information for all health care facilities in which their packaging systems may be used. The cycle parameters are frequently a function of the device to be sterilized, the loading, as well as the specific sterilization equipment at each health care facility. It may be more appropriate for the agency to require a statement of cycle limitations such as temperature extremes, vacuum change limits or other fragile parameters specific to the packaging system. …see Section II, Para. E, Sub.4 & 5 (page 11) for similar requirements.

9. Section II, Para. D (page 9) - Comparison of the new Device with the Predicate

   Comment: Porosity should be used to replace air permeance.

   Comment: Toxicological Properties should reference Sterilant Residue levels rather than limits. The manufacturer should report on the levels of sterilant residue after standard cycle sterilization rather than set performance criteria on behalf of the user.

   The draft states in the Microbial barrier properties annotation that "To maintain sterility, your device should be impermeable to microorganisms".

   Comment: The microbial barrier definition should be labeled Package integrity and microbial barrier. The statement noted above cannot be measured as an absolute impermeable condition. The statement should be replaced with "the microbial barrier properties should be reported on the materials:.

   Under Aeration time the agency states that the "device should permit adequate aeration of the sterilant"

   Comment: The agency has not defined the level of "adequate". The requirement should be to report the level of sterilant residue after aeration of the container under standard sterilization and aeration cycles.

10. Section II, Para. E, Sub. 1 (page 10) - The example for Pouches references "tyvek"

    Comment: Tyvek® is a registered trademark of E. I. DuPont De Nemours and should be designated as such with a reference footnote.

11. Section II, Para. E, Sub. 4 (page 14) - Biological indicator. The draft states that " the labeled exposure time for the sterilization packaging systems should be at least double the minimum exposure time." And " The established sterilization time should be within the standardized cycle time of the sterilizers routinely used in the health care setting."

    Comment: The use of double as the standard by the agency appears arbitrary and should be explained. In addition, the two statements above may be in conflict and a mechanism for resolving should be addressed by the agency.

12. Sec. III, Para. B, Sub. 1 (pages 14 & 15) - The term "performance" is used to describe the type of testing needed to evaluate different material characteristics.

    Comment: "Performance" testing has historically referred to subjecting a sample to stresses it would encounter during its use. The term "characteristic" testing would better describe the type of testing used to evaluate the physical attributes or characteristics of the material.

13. Sec. III, Para. B, Sub. 2 (page 15) – Again the term "performance" is used to describe the type of testing needed to evaluate different material characteristics.

    Comment: Recommend replacing "performance" with "characteristic".... see above.

14. Sec. III, Para. B, Sub. 3 (page 15) – The draft states that "The American Society for Testing and Materials (ASTM) has published several standards for **package integrity** using physical test methods".
    Comment: The ASTM standards list for medical packaging includes many that are broader than integrity tests. The agency should consider revising the sentence to state that ASTM International (American Society for Testing and Materials) has published several test methods for evaluating sterile barrier packages and materials.

15. Sec. III, Para. B, Sub. 3 (pages 15 & 16) Standards

    Comment: The Standard Test Method for Microbial Ranking of Porous Materials (Exposure Chamber Method) F1608:1995 should be corrected to F1608€: 1995

    Comment: The agency should consider adding the following ASTM International methods. These standards provide additional valuable resources for sterile package and material testing and are either being considered for addition to the list of FDA recognized standards or are already listed **D726-94** *Standard Test Method for Resistance of Nonporous Paper to Passage of Air (Gurley Porosity Test)* **D903-98** *Standard Test Method for Peel or Stripping Strength of Adhesive Bonds*, **F1980-99e1** *Standard Guide for Accelerated Aging of Sterile Medical Device Package* ***F2096*-01** *Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Test)* **F2097-01** *Standard Guide for Design and Evaluation of Primary Packaging for Medical Products*

16. Sec. III, Para. B, Sub. 3 (page 16) The draft states that D3078 "the Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission is the **only** standard for physical testing of whole package integrity".

    Comment: Both **F1886-98** *Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection* and **F1929-98** *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration* are accepted and commonly used in the device manufacturing community to evaluate not only seals but for other package integrity anomalies. The statement should be corrected. In addition, F2096-01 *Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Test)* should be added as a cited integrity test.

17. Sec. III, Para. B, Sub. 3 (page 16)
    Comment: The Agency should consider adding a reference to ANSI/AAMI/ISO **11607-1997** *Packaging for terminally sterilized medical devices* and AAMI TIR No. **22 - 1998** *Guidance for ANSI/AAMI/ISO 11607-1997 Packaging for terminally sterilized medical devices.* These documents provide additional valuable resources for sterile package and material testing and are listed as FDA recognized standards.

(Note: AN**SI/AAMI/ISO 11607** appears in Section VI. References but does not appear anywhere in the body of the document)

18. Sec. III, Para. B, Sub. 5 (page 17) – The draft states that "No claims can be made for maintenance of sterility unless the cassette is wrapped with sterilization wrap".

    Comment: In addition to a sterilization wrap, they may be placed in a rigid container, pouch or reel good. The agency should expand the definition to include the alternatives.

19. Sec. III, Para. D Sub. 5 (page 19) Aeration time and EO sterilization

    Comment: The limits of use should be defined based on number of uses and/or number of cycles.

20. Sec. III, Para. F Sub. 5 (page 19) Material Compatibility

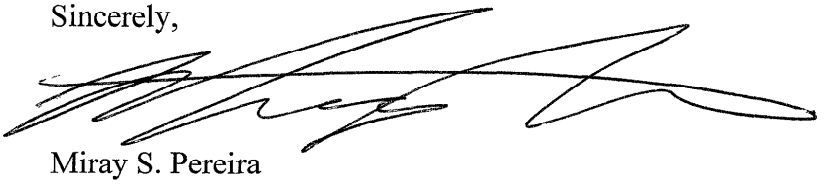
    Comment: The properties evaluated should be consistent with those used in the comparison with the predicate in Section II, Para. D. Thickness variation and durability should be removed.

21. Section VI. (pages 25 & 26) – References

    Comment: Reference documents listed in Sec. III, Para. B, Sub. 3 (pages 15 & 16) should be added in this section as well as the AAMI TIR **No. 22 – 1998** *Guidance for ANSI/AAMI/ISO 11607-1997 Packaging for terminally sterilized medical devices*

    Comment: The first two references to **A**ssociation for the **A**dvancement of **M**edical **I**nstrumentation) are incorrectly stated as " ANSI/AMMI" and should be corrected to "ANSI/AAMI".

Sincerely,



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